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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,162	01/13/2005	Kevin S. Brandt	FC-11-PUS	5437

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EXAMINER	
HOWARD, ZACHARY C	

ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
12/28/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/521,162	BRANDT, KEVIN S.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *40 and 41* is/are allowed.

6)☒ Claim(s) *32-34,37-39 and 44* is/are rejected.

7)☒ Claim(s) *32-39,42 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 10/5/07 has been entered in full. Claims 1-31 are currently or previously canceled. New claims 32-44 are added.

Claims 32-44 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (7/16/07).

The objection to the specification at pg 2 regarding the priority statement is *withdrawn* in view of Applicants' amendments to the specification. However, please see the new objection to the specification for containing new matter, necessitated by Applicants' amendments, set forth below

All rejections of claims 2, 4, 6, 12, 14, 15, 19-24 and 26-31 are moot in view of Applicants' cancellation of these claims.

New rejections necessitated by Applicants' amendment

Specification

The disclosure is objected to because:

The amendment filed 10/5/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows: "all of which are incorporated by reference herein" in reference to U.S. Provisional Patent Applications 60/426,601 and 60/319,402. A preliminary amendment was filed on the same date (1/13/05) of the original specification that added a priority statement to this first line of the specification. This priority statement claimed priority for the instant application to the above provisional applications but did not incorporate said provisional application by reference. As noted in MPEP 608.01(p).I.2, "Incorporating by reference material that was not incorporated by reference on filing of an application may

introduce new matter". As said provisional applications may include subject matter beyond what it is claimed in the instant application, the incorporation by reference of said provisional applications (rather than just claiming priority) is considered to introduce new matter into the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claims 32-39, 42 and 43 are objected to because of the following informalities:

(1) In each of claims 32 and 34, the word "complementary" is misspelled as "complimentary". It is noted that the specification as originally filed and the previous listing of claims (5/18/07) correctly spell the word as "complementary".

(2) Claims 33 and 37 are objected to because neither of SEQ ID NO: 1 or 2 encodes the protein of SEQ ID NO: 4, 7 or 12 (as required by the parent claim).

(3) New claim 34 recites "An isolated nucleic acid molecule consisting a nucleic acid sequence..." This recitation is missing the word "of" between "consisting" and "a".

Appropriate correction is required.

(4) New claims 35, 36, 38, 39, 42 and 43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

(5) Claim 35 depends from claim 34, but is broader in scope. Specifically, claim 34 is limited to isolated nucleic acids that consist of a nucleic acid sequence encoding a protein consisting of SEQ ID NO: 4, 7 or 12. Claim 35 is broader because it further includes any fragment of claim 34 that is 35 nucleotides or longer.

Claims 36, 38, 39, 42 and 43 are similarly broader than the parent claim from which they depend.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32, 34, 37 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

(1) an isolated nucleic acid molecule comprising a nucleic acid sequence fully complementary to the nucleic acid sequence of part (a) of claim 32;

(2) an isolated nucleic acid molecule consisting of a nucleic acid sequence fully complementary to the nucleic acid sequence of part (a) of claim 34; and

(3) a method to detect an inhibitor of octopamine receptor activity, said method comprising (a) contacting an isolated protein comprising SEQ ID NO: 12 with a putative inhibitory compound in the presence of octopamine under conditions in which, in the absence of said compound, said protein has octopamine receptor activity and (b) determining if said protein has octopamine receptor activity;

does not reasonably provide enablement for

(1) an isolated nucleic acid molecule comprising a nucleic acid sequence complementary to the nucleic acid sequence of part (a) of claim 32;

(2) an isolated nucleic acid molecule consisting of a nucleic acid sequence complementary to the nucleic acid sequence of part (a) of claim 34; or

(3) a method to detect an inhibitor of octopamine receptor activity, said method comprising (a) contacting a protein comprising SEQ ID NO: 12, with a putative inhibitory compound in the absence of octopamine under conditions in which, in the absence of said compound, said protein has octopamine receptor activity and (b) determining if said protein has octopamine receptor activity.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

(1) New claims 32 and 34 recite "a nucleic acid sequence complimentary [sic] to the nucleic acid sequence of (a)". In contrast, cancelled claims 2 and 4 recited "a nucleic acid molecule fully complementary to the nucleic acid molecule of (a)" (see 5/18/07 Listing of Claims). The absence of the word "fully" in new claims 32 and 34 indicates that the claimed complementary nucleic acid need not be fully complementary. As such, the claims encompass nucleic acid sequence fragments as small as two nucleic acids that are complementary to a portion of "(a)". Furthermore, with respect to claim 32, the claims encompass nucleic acid variants comprising said fragments, such as a variant of SEQ ID NO: 12 with one or more changes to the encoded protein.

As set forth in the previous Office Action (7/16/07; pg 4-14) for cancelled claim 2, due to the large quantity of experimentation necessary to generate the large number of variants recited in the claims and screen the same for octopamine-binding activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 37 is included in this rejection because it depends from claim 34 and encompasses fragments of a nucleic acid sequence complementary to SEQ ID NO: 1, 2, 3, 5, 6, 8, 10, 11 and 13 that are as small as two nucleic acids in length.

(2) New claim 44 encompasses a method to detect an inhibitor of octopamine receptor activity, said method comprising (a) contacting a protein comprising the amino acid sequence of SEQ ID NO: 12 with a putative inhibitory compound under conditions in which, in which the absence of said compound, said protein has octopamine receptor activity and (b) determining if said protein has octopamine receptor activity. The claim requires that the method be practiced “under conditions” in which the receptor has octopamine receptor activity. However, as set forth previously for canceled claim 15 (see the 7/16/07 Office Action, pg 11-12) the specification does not provide any

guidance as to conditions in which octopamine receptor activity can be produced without the presence of octopamine. In order to practice the claimed method without octopamine, the skilled artisan would first need to engage in experimentation to find other conditions in which the protein of SEQ ID NO: 12 has "octopamine receptor activity". Such experimentation would be undue in view of the lack of guidance as to other ligands that would induce receptor activity and the need to screen large numbers of compounds in order to determine whether or not any other ligands even exist. Due to the large quantity of experimentation necessary to screen ligands for those that produce octopamine receptor activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art fails to teach another ligand for the receptor of SEQ ID NO: 12, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Furthermore, new claim 44 does not limit the protein used in the method to an "isolated protein" (as in the method of now cancelled claim 15). As such, new claim 44 encompasses methods of screening wherein the protein comprising SEQ ID NO: 12 is expressed in non-isolated host cells, such as in transgenic animals. Methods of using transgenic animals lack enablement for the reasons set forth at pg 12-13 of the 7/16/07 Office Action.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 32, 34 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 32, 34 and 37 are genus claims because the claims are directed to variant isolated nucleic acid molecules. Each genus is highly variant because a

significant number of structural differences between genus members are permitted. The scope of each claimed genus is described above in the section titled, "Claim Rejections - 35 USC § 112, 1st paragraph, enablement".

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions, of the genus of encoded polypeptides related to SEQ ID NO: 12. There is not even identification of any particular portion of the structure that must be conserved. Structural features that could distinguish encoded polypeptides in the genus from others in the protein class are missing from the disclosure. The specification and claims do not provide any description of what changes should be made. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides and polypeptides encompassed. Thus, no identifying characteristics or properties of the instant polypeptides are provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (pg 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (pg 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only (1) an isolated nucleic acid molecule comprising a nucleic acid sequence fully complementary to the nucleic acid sequence of part (a) of claim 32; and (2) an isolated nucleic acid molecule consisting of a nucleic acid sequence fully complementary to the nucleic acid sequence of part (a) of claim 34, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (pg 1115).

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 depends from claim 32, and claim 37 depends from claim 34. The parent claims are limited to an isolated nucleic acid molecule comprising a nucleic acid sequence encoding a protein comprising (claim 32) or consisting (claim 34) of SEQ ID NO: 4, 7 or 12, or a compliment thereof. Dependent claims 33 and 37 include SEQ ID NO: 1 and 2 as nucleic acid sequences that encode SEQ ID NO: 4, 7 or 12. However, as set forth in the previous Office Action (pg 6), "The protein encoded by SEQ ID NO: 1 is not disclosed in the specification but would consist of approximately 5% of the full-length protein (37 of 712 amino acids)." SEQ ID NO: 2 is the compliment of SEQ ID NO: 1. Neither of SEQ ID NO: 1 or 2 encodes the protein of SEQ ID NO: 4, 7 or 12.

The remaining claims are rejected for depending from an indefinite claim.

Conclusion

Claims 40 and 41 are allowable.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646